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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,337	12/11/2003	Harry S. Sowden	MCP0293-DIV	1381

27777 7590 03/16/2006

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EXAMINER	
DAVIS, ROBERT B	

ART UNIT	PAPER NUMBER
1722	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,337	SOWDEN ET AL.	
	Examiner	Art Unit	
	Robert B. Davis	1722	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 27-39* is/are pending in the application.

4a) Of the above claim(s) *27-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 12-20* is/are rejected.

7)☒ Claim(s) *7-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-20 in the reply filed on February 6, 2005 is acknowledged.

2. Claims 27-39 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 6, 2005.

Specification

3. The disclosure is objected to because of the following informalities:

On line 27 of page 21, there is a blank space after Serial No. Applicant is required to fill-in the application corresponding to docket number MCP 274.

All related applications listed in the specification must be updated to reflect Patent numbers or abandonment.

Appropriate correction is required.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not include the language "powder has a minimum orifice diameter of flowability greater than about 30 mm as measured by the Flodex test". The specification on page 20, recites greater than 10, preferably 15 and more preferably 25, but lacks antecedent basis for 30. Since 30 was filed in the original claims and therefore does not constitute new matter.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 13-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 and 40-47 of copending Application No. 10/743,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 13 of the instant application is fully encompassed by claim 13 of 10/743,364.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 13, 15, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Doepel (4,292,017: figures 1, 2 and 4; column 2, lines 1-19 and column 5, line 53 to column 6, line 24).

Doepel teaches an apparatus for forming compressed dosage forms (tablets), the apparatus comprising: a suction source (vacuum pump-column 5, lines 61-63); a die cavity (38) having a first port for placing the die cavity in flow communication with said suction source (top opening of the die) to said die cavity, and a second port for placing the die cavity in flow communication with a supply of powder (bottom opening of the die), whereby the suction source assists said powder in flowing into the die cavity (see column 2, lines 1-9), a filter (116, 118, 119) disposed between the suction source (attached to conduit 120-see column 5, lines 53-67), a punches (40, 42) for compressing the powder in the die cavity so as to form compressed tablets (figure 5); and a powder recovery system for removing excess powder from the filter, which is a source of compressed air upwardly and the purged product is drawn off by vacuum (column 6, lines 10-24). The vacuum source above the filter to collect the purged powder blown out of the filter is being considered a recovery system. The examiner is drawing a clear line between recovery and recycling. Accordingly, claim 15 does not require recycling structure. It is inherent that the punches have the capability of operating at a force of 20 kN. The die is disposed proximal to the die cavity as described above and shown in figure 4.

9. Claims 1, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Belousov et al (Soviet reference 662370 A: figures 1-3 and the English abstract.

Belousov et al teach an apparatus for compression molding of dosage forms (tablets), the apparatus comprising: a suction source (vacuum from the abstract attached to hose (16), a die cavity (4) having a first port (bottom opening of the die) for placing the die cavity in flow communication with the suction source (during the filling period-abstract), a second port (top opening of the die) for placing the die cavity in flow communication with a supply of powder, such that the suction source assists powder in flowing into the cavity; a filter (19) disposed between the suction source and the second port. The apparatus is inherently capable of operating at a force of 20 kN. With regards to the method claims, the die is isolated from the filter by moving the dies from the filling table to the compression table.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3, 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al –370 taken together with Campbell (3,430,532: figures 2-6 and column 2, lines 3-28).

Belousov et al disclose all claimed features except for the second port being located in a wall of the die wherein the opening is closed upon upward movement of a bottom plunger or the use of a feed shoe which covers a plurality of dies on a die table as it is rotated past the feed shoe.

Campbell discloses a compression molding machine having a die (18) having openings (98) connected to a vacuum source for assisting in the quick, uniform loading of the die and a feed head (84) covering a plurality of dies (18) on a die table (86).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Belousov et al by using a lateral opening of the die connected to a vacuum source for assisting in filling of the die as disclosed by Campbell for the purpose of assuring uniform filling of the plurality of dies. It would have been further obvious to modify the apparatus of Belousov et al by using a feed head that covers a plurality of dies on a die table as disclosed by Campbell for the purpose of feeding particulate material to a plurality of dies.

13. Claims 4-6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doepel taken together with) taken together with Bullock (5,667,158: figures 1 and 2; column 1, lines 16-30; and column 3, lines 31-47).

Doepel discloses all claimed features including purging of the filter with compressed air into the die, but fails to disclose or suggest recycling of the purged material.

Bullock et al disclose a reclaim system for use with a pharmaceutical tablet compression machine, comprising: a filter (114) for collecting material dust, a compressed air source (128) to purge dust from the filter and a canister (112) which feeds dust back to a raw material source (C). The reference fulfills a long felt need for reusing raw material collected from the compression molding machine to save material costs.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Doepel by adding a mechanism for recycling collected raw material as disclosed by Bullock et al for the purpose of saving on material costs by collecting discarded material from a compression molding machine.

14. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al taken together with Bullock et al (5,667,158: figures 1 and 2; column 1, lines 16-30; and column 3, lines 31-47).

Belousov et al disclose an apparatus for compression molding of dosage forms (tablets), the apparatus comprising: a suction source (vacuum from the abstract attached to hose (16), a die cavity (4) having a first port (bottom opening of the die) for

placing the die cavity in flow communication with the suction source (during the filling period-abstract), a second port (top opening of the die) for placing the die cavity in flow communication with a supply of powder, such that the suction source assists powder in flowing into the cavity; a filter (19) disposed between the suction source and the second port. The reference fails to disclose a powder recovery system to purge captured particulate in the filter.

Bullock et al disclose a reclaim system for use with a pharmaceutical tablet compression machine, comprising: a filter (114) for collecting material dust, a compressed air source (128) to purge dust from the filter and a canister (112) which feeds dust back to a raw material source (C). The reference fulfills a long felt need for reusing raw material collected from the compression molding machine to save material costs.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the apparatus of Belousov et al by adding a mechanism for recycling collected raw material as disclosed by Bullock et al for the purpose of saving on material costs by collecting discarded material from a compression molding machine.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Belousov et al (-370) taken together with Royce (5,273,758: column 2, lines 34-54; column 3, line 64 to column 4, line 16; and column 5, lines 10-21).

Belousov et al disclose all claimed features except for the use of dry blending to mix the tablet components prior to compression, the percentage medicant used, the particle size used or the standard deviation of the weight of the tablets produced.

Royce discloses that directly compressed dosage forms are prepared by dry blending of particles of polyethylene oxide (binder material) and a medicant (column 4, lines 9-13). The reference states that mixture is applied to a tableting machine and uses a compression force of about 0.5-10 tons (4.4-89 kN) is applied.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the process of Belousov et al by dry blending the particles of the tablet composition as disclosed by Royce for the purpose mixing the constituents before tableting.

Allowable Subject Matter

16. Claims 7-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter:

None of the prior art of record teaches or suggests method of claim 1 wherein the powder has a minimum orifice diameter of flowability greater than about 30 mm as measured by the Flodex test. The closest prior art (Guo et al 6,623,754) discloses Flodex numbers of a lesser diameter, but does not disclose or suggest a flowability number greater than about 30 mm. Guo et al also does not disclose or suggest vacuum filling during the compression molding process.

In regards to claim 10, none of the prior art teaches or suggests the method of claim 1 wherein the powder comprises at least 85 percent by weight of medicant and has an average particle size of about 50 to about 300 microns. Guo et al recites particles sizes in the claimed range and Royce discloses a weight percent of medicant, but neither reference suggests a combination of these values without improper picking and choosing from the prior art and hence hindsight.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The remaining references illustrate the state of the art of compression molding of dosage forms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 571-272-1129. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Davis
Primary Examiner
Art Unit 1722

3/14/04